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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,418	02/22/2002	Kyung-Soo Hahm	428.1014	1012

7590 07/03/2003

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,418	HAHM ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-21* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11-20* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' amendment filed May 22, 2003 is acknowledged and has been entered. Claim 21 has been added.

2. Applicant's election with traverse of Group I, claims 9, 10 and 21, in Paper No. 7 (filed 5/22/03) is acknowledged. The traversal is on the ground(s) that a search of the art that is directed to the invention of elected Group I will also very likely overlap a search strategy directed to the subject matter of the invention of the non-elected groups. Applicants have set forth example that a search of the modified CA-MA2 peptide of claim 9 would also overlap searches that might be directed to the pharmaceutical composition comprising a modified CA-MA2 peptide of claim 11. Upon further review of the claims and consideration of Applicants' arguments, Groups I and II have been combined. Claims 9-14 and 21 will be examined in the present application. However, the restriction requirement is maintained for the other inventions for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicants should file an English translation of Korean Patent Application No. 2001-57837. The effective filing date for the pending US patent application is February 22, 2002.

5. In view of the papers filed September 5, 2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by deletion of Hee Nam Kim.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

6. The disclosure is objected to because of the following informalities: misspelled words, for example page 12, line 7, "Bascilus" should be "*Bacillus*" and page 22, line 25, "Stapliococus" should be "*Staphylococcus*". There may be others, please review the specification in its entirety. Appropriate correction is required.

7. Claims 10 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of the Markush group language. Does Applicant intend that the modified CA-MA2 peptide can have at least any one of the possible thirteen (13)

substitutions as set forth in lines 3-5 of claim 12 for example or does the peptide have to have all thirteen substitutions?

8. Claims 9-14 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite a modified CA-MA2 peptide and a pharmaceutical composition comprising said modified CA-MA2 peptide. The specification has set forth how to make the claimed invention, however the specification does not teach how to use the claimed peptide and pharmaceutical composition.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. MPEP 2164.01(c) The present specification has not taught how to use the claimed pharmaceutical composition. A pharmaceutical use would be any use, other than as food, wherein a substance is used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals. The following are examples of "pharmaceutical uses": administering vitamin supplements (preventing disease); using labeled antibodies for *in vivo* imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection).

However, such a definition is not so broad as to cover ***any*** use of a substance on or in the body of a human or animal, only those uses intended to prevent,

diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

Where an antigenic substance is administered to a human or animal for the purpose of producing antibodies wherein the resultant antibodies are intended to protect the individual from contracting a disease, i.e., vaccination. This is considered a pharmaceutical use because the antigenic substance is being used to prevent a disease in the human or animal to which the antigenic substance was administered.

However, when an antigenic substance is administered to an animal to produce antibodies wherein the resultant antibodies are intended to be collected from the animal and used in various ways, e.g., in an assay system or in passive immunization, this is not a pharmaceutical use. The antigenic substance is not being used to prevent, diagnose, alleviate, treat, or cure a disease in the animal to which the antigenic substance was administered. The animal is merely being used as a bioreactor to make the antibodies that will ultimately be used, maybe even in the prevention, diagnosis, alleviation, treatment, or cure a disease in another animal.

Thus, to enable a pharmaceutical use for a substance (i.e. modified CA-MA2 peptide), the specification must teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure a disease in the animal to which the substance is administered.

Applicants have not set forth any data they show that when the modified CA-MA2 peptide in a pharmaceutical composition is administered to an animal or human with be effective in the treatment, prevention, alleviation or cure of bacterial infection, fungal infection or act as an anti-cancer agent. The

specification has shown by in vitro methods that the claimed peptide has anti-bacterial activity, anti-fungal activity and anti-cancer activity. However, there is no pharmaceutical use of these modified CA-MA2 peptides. When applicant is claiming a pharmaceutical composition, applicant must enable a pharmaceutical use. In this case, while preventing bacterial infection would be a pharmaceutical use, the facts tell us that such a use is not enabled. The pharmaceutical use must occur within the animal to which the compound is administered for the prevention, diagnosis, alleviation, treatment, or cure of disease.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin et al 1998 (Biochemistry and Molecular Biology International, 44/6:1119-1126), Lee et al 1999 (J. Biochem. Mol. Biol. And Biophys., 2:243-248), Shin et al 2000 (J. Biochem. Mol. Biol. And Biophys., 4:135-145), Oh et al 2000 (Biochemistry, 39:11855-11864), Kang et al 1998 (J. Peptide Research, 52:45-50), Shin et al 1999 (J. Peptide Research, 53:82-90) or Shin et al 1997 (J. Peptide Research, 50:279-285).

The claims are directed to a modified CA-MA peptide, wherein at least one amino acid has been substituted as set forth in claim 10 for example.

Shin et al 1998 discloses modified CA-MA peptides (abstract; p. 1120-21; p. 1123). Table 1 discloses different CA-MA analogues (i.e. modified CA-MA

peptides); see for example Peptides A3, A4, A6, A9, A10, A11, A12 and A13 of Table 1.

Lee et al 1999 discloses modified CA-MA peptides (abstract; p. 243). Table 1 discloses different CA-MA analogues (i.e. modified CA-MA peptides); see for example Analogues 3, 5 and 7 of Table 1.

Shin et al 2000 discloses modified CA-MA peptides (abstract). Table 1 discloses different CA-MA analogues (i.e. modified CA-MA peptides); see for example Peptides P3, P4, P6, P9, P11, P12 and P13 of Table 1.

Oh et al 2000 discloses modified CA-MA peptides (abstract). Table 1 discloses different CA-MA analogues (i.e. modified CA-MA peptides); see for example Peptide P2 of Table 1.

Kang et al 1998 discloses modified CA-MA peptides (abstract). Table 1 discloses different modified CA-MA peptides; see for example Peptides A1, A2. A3, A6, A8 and A9 of Table 1.

Shin et al 1999 discloses modified CA-MA peptides (abstract; p. 83). Table 2 discloses different CA-MA analogues (i.e. modified CA-MA peptides); for example amino acid position 10 has been substituted by proline.

Shin et al 1997 discloses modified CA-MA peptides (abstract). Table 1 discloses different CA-MA analogues (i.e. modified CA-MA peptides); see for example Peptides P4, P6 and P8 of Table 1.

The prior art discloses the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' peptides with the peptides of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the

claimed peptides and the peptides of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

NITA MINNIFIELD
PRIMARY EXAMINER
AU 1645
6/25/03